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Description

BACKGROUND OF THE DISCLOSURE

The present invention is in the field of implantable medical devices, and more particularly, is directed to devices useful as prosthetic menisci.

The meniscus acts in the knee joint as a crucial stabilizer, a mechanism for force distribution, and a lubricant in the area of contact between the tibia and femur. Without the meniscus, stress concentration occurs in the knee in conjunction with abnormal joint mechanics, and premature development of arthritic changes from collagen stress occurs.

In the prior art, treatment of injured or diseased menisci has generally been both by surgical repair and by excision. With excision, regeneration of meniscal tissue may occur. Additionally, it is known that meniscal fibrochondrocytes have the ability to migrate into a defect filled with a fibrin clot and form tissue apparently similar to normal meniscal fibrocartilage. When an adequate matrix scaffold is present within a meniscal defect, such meniscal fibrocartilage may be formed. Meniscal tissue is also capable of self-repair when exposed to bleeding tissues, and additionally, it is also known in the prior art that meniscal cells in tissue culture are capable of cell division and matrix synthesis. Replacement of an injured meniscus in an otherwise healthy joint may prevent arthritic changes and may stabilize the joint. In diseased joints, replacement of the meniscus may reduce the progression of the disease process, and may provide pain relief. Allografting or meniscal transplantation, is one method of replacement which has been executed both in dogs and in humans. However, this approach has been only partially successful over the long term due to the host's immunologic response to the graft, to failures in the cryopreservation process, and to failures of the attachment sites.

In alternative prior art replacement approaches, menisci have been replaced with prostheses composed of artificial materials. Such prostheses have been constructed of purely artificial materials in order to minimize the possibility of an immunological response. In addition, the use of such materials is believed to be advantageous because it permits construction of a structure which can withstand the high and repeated loads which are encountered in the knee joint, and because it can alter the joint mechanics in beneficial ways that biological materials would not tolerate. For example, a Teflon net has been used to replace the resected meniscus of a dog upon which fibrous ingrowth or regeneration was observed, although accompanied by significant chondral abrasion. A prosthetic meniscus has also been constructed from resilient materials such as silicon rubber or Teflon with reinforcing materials or stainless steel or nylon strands (U.S. Patent No. 4,502,161). In addition, a meniscal component has been made from resilient plastic materials as disclosed in U.S. Patent No. 4,085,466. Reconstruction of meniscal lesions have been attempted with carbon-fiber-polyurethane-poly (L-lactide) with minimal success.

Generally, the replacement of meniscal tissue with structures consisting of artificial materials has been unsuccessful, principally because the opposing articular cartilage of human and animal joints is fragile. The articular cartilage in the knee will not withstand abrasive interfaces, nor compliance variances from normal, which eventually results from the implantation of prior art artificial menisci. Additionally, joint forces are multiples of body weight which, in the case of the knee and hip, are typically encountered over a million cycles per year. Thus far, prior art artificial menisci have not been soft, durable, or lubricative enough, nor have they been able to be positioned securely enough to withstand such routine forces.

Prostheses, in general, have been devised out of at least some of the constituents of the structures which they are replacing, or out of materials not considered to be immunogenic to the body. For example, Yannas et al., fashioned endodermal implants, synthetic epidermis (U.S. Patent No. 4,060,081), and sciatic nerve guides out of collagen and glycosaminoglycans, which are biochemical constituents of many body organs. By adjusting the pore size and axes of the pores and fibers comprising these structures, regrowth could be stimulated, and was, indeed, observed. Further regrowth has been advanced by seeding of the nerve guide with Schwann cells prior to implantation. However, even with the foregoing technologies which have been applied to the reconstruction of anatomical structures other than knee joints, a structure suitable as a prosthetic meniscus and constructed from natural materials has not been developed in the prior art.

GB-A-1 515 963 discloses composite materials made of collagen polymers cross-linked to differing degrees to a mucopolysaccharide, thereby to obtain significant degrees of resistance to resorption. The composite materials are intended for the production of sutures and prostheses resistant to resorption, in particular vascular prostheses that must be blood compatible.

It is an object of this invention, however, to provide a meniscal replacement or prosthesis, especially a meniscal replacement, or prosthesis, which does not interfere with normal joint motion, which would lead to either a reduced range of motion, or focal concentration of force at other sites within the joint and therefore

progressive cartilage destruction.

The invention herein seeks to provide a meniscal replacement or prosthesis which is biomechanically able to withstand normal joint forces and is able to function at those loads to protect the cartilage and stabilize the joint.

Still further, the invention seeks to provide a meniscal replacement or prosthesis which acts as a scaffold for meniscal fibrochondrocyte infiltration, and which is subsequently replaced.

A meniscal replacement or prosthesis according to the invention may beneficially be composed of biocompatible materials having an organization equivalent to that of the normal meniscus; thereby not evoking an immunologic reaction, nor aggravating other joint structures.

Desirably, the meniscal replacement or prosthesis is implantable by standard operative techniques, preferably transarthroscopically.

The present invention, provides a prosthetic meniscus having a matrix of biocompatible bioresorbable fibers, which may permit ingrowth of meniscal fibrochondrocytes, for supporting natural meniscal load forces.

According to the present invention, there is provided a prosthetic meniscus comprising a dry porous matrix of biocompatible bioresorbable fibers, which fibers include natural polymers or analogs or mixtures thereof, characterised by the fiber matrix being adapted to have in vivo an outer surface contour substantially the same as that of a natural meniscus, and comprising a three-dimensional array of Type I collagen fibers interspersed with glycosaminoglycan molecules, wherein said collagen fibers are present at a concentration of 65%-98% by dry weight, wherein said glycosaminoglycan molecules are present at a concentration of 1%-25% by dry weight, and wherein at least a portion of said molecules provide glycosaminoglycan crosslinks between said collagen fibers.

The present invention provides a structure for implantation into the knee joint which assumes the form and role of a meniscus. This prosthetic meniscus may also promote regrowth of meniscal tissue and may provide a scaffold for the regenerating tissue.

The prosthetic meniscus is generally a three dimensional array of collagen fibers interspersed and crosslinked with glycosaminoglycan molecules. The array may have a simple crescent-shaped wedge, cylindrical pad, or other shape. The structure comprises about 65-95% Type I collagen and about 1-25% glycosaminoglycans by dry weight, the proportions of which may be constant throughout the structure or may be variable.

In the structure, the collagen fibers may be randomly orientated throughout the structure, or ordered at specified regions. Alternatively, the fibers may assume substantially circumferential and radial orientations at specified regions of the structure or may be found uniformly throughout the prosthetic meniscus.

The glycosaminoglycans (GAGs) consist of at least one of the group of molecules comprising chondroitin 4-sulfate; chondroitin 6-sulfate; keratin sulfate; dermatan sulfate; heparin sulfate; and hyaluronic acid. These GAGs may be uniformly dispersed throughout the prosthetic meniscus as individual molecules, or may be present in differing amounts in different regions of the structure.

However, at least a portion of the GAG molecules comprising the prosthetic meniscus are constituents of chemical crosslinks which bridge neighboring collagen fibers. These crosslinks are composed of at least one polymerized GAG molecule, and have a molecular weight in the range 800-60,000 daltons.

In various forms of the invention, GAG crosslinks may be uniformly dispersed throughout the prosthetic meniscus at a density of less than about 0.9 but greater than about 0.5, as expressed by the 3-hydroxypyridium crosslink/collagen molar ratio, thereby permitting the ingrowth of regenerating meniscal tissue, and eventually providing a fluidic impedance similar to that of normal meniscus of about 1/8.13 x 10^{-16} m^4/N.S.. In other forms of the invention, the density of these crosslinks may be greater than about 0.9, providing a fluidic impedance of greater than about 1/8.13 X 10^{-16} m^4/N.S, and thereby being dense enough to act as a protective and lubricating barrier between the femur and tibia. These crosslinks may also be located with varying densities at specified regions of the prosthetic meniscus, permitting greater physical strength at anticipated high stress points.

In accordance with another aspect of the invention, the prosthetic meniscus may further comprise a mesh composed of a dissolvable, nonimmunogenic material which is attached to portions of the outer surface of the prosthetic meniscus. The mesh, which may be in the form of suture material, aids in the successful implantation of the prosthetic meniscus into the knee joint by providing a temporary anchoring mechanism.

BRIEF DESCRIPTION OF THE DRAWING

The foregoing and other objects of this invention, the various features thereof, as well as the invention, itself, may be more fully understood from the following description, when read together with the accompanying drawings:

Fig. 1 shows a simplified diagramatic representation of a humaniod knee joint, with menisci in native positioning;

Fig. 2 shows a perspective view of an exemplary prosthetic meniscus in accordance with the present invention;

Fig. 3 shows a perspective radial section of the prosthetic meniscus of Fig. 2;

Fig. 4 shows a perspective view of an alternative embodiment of the present invention;

Fig. 5 shows a sectional view along line 5-5 of the prosthetic meniscus of Fig. 4.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Fig. 1 shows a diagramatic representation of the normal postioning of medial meniscus 7 and collateral meniscus 8 in the human knee joint 3 between the femur 2 and tibia 4.

Figs. 2 and 3 show an exemplary prosthetic meniscus 10 embodying the present invention. The prosthetic meniscus 10 is adapted for implantation in the normal location in the knee joint.

Generally, the prosthetic meniscus 10 has the shape of a crescent-shaped wedge comprising a relatively wide central region 12 between two narrow distal regions 14 and 16. In the preferred form, the wedge has height A and its peripheral edge of approximately 10.2 mm (0.4 inches), a height D at its central point of approximately 5.1 mm (0.2 inches), and a radius C of approximately 25.4 mm (1.0 inches). The crescent shaped wedge subtends an angle B substantially in the range of about 25 to about 45 degrees, and preferably of about 30 degrees.

The prosthetic meniscus is composed essentially of collagen and glycosaminoglycans (GAGs), and more particularly, of a three-dimensional array of collagen type I fibers interconnected via crosslinks consisting of polymerized GAG molecules. In other embodiments, additional GAG molecules may be present outside of the crosslinked GAGs.

In the preferred embodiment, the collagen fibers in the array are ordered in substantially circumferentially-extending and substantially radially-extending orientations, with the density of fibers being substantially uniform throughout the array. However, in other embodiments, the array of collagen fibers may be unordered. In either configuration, ordered or unordered, the density of said fibers may be non-uniform, particularly having high densities at points in the prosthetic meniscus at which high stress levels are anticipated, such as at the distal regions 14 and 16.

The GAG crosslinks have a molecular weight in the range of 600 to 80,000 daltons, and are composed typically of at least one of the group of GAG molecules consisting of chondroitin 4-sulfate; chondroitin 6-sulfate; keratin sulfate; dermatan sulfate; heparin sulfate; and hyaluronic acid. The dispersion of GAG crosslinks is preferably uniform, but may be more concentrated at anticipated points of high stress, typically at the distal regions 14 and 16, and less concentrated in the central region 12. In such configurations, the GAG concentration may be in the range of about 3-25% in the distal regions 14 and 16, and in the range of about 1-10% in the central region 12. However, when uniform, the dispersion of GAG crosslinks throughout the prosthetic meniscus may be, for example, in the range of about 1-15%.

In the preferred embodiment, the density of the crosslinks is relatively low (for example, on the order of about 0.7 crosslink/collagen molar ratio) in the array to permit ingrowth of regenerated meniscal tissue. In other embodiments, the density of said crosslinks may be relatively high (for example, on the order of 0.9 crosslink/collagen ration) to provide cushioning, lubrication and support for the knee joint and to slow vascular ingrowth, thereby diminishing the rate of scaffold resorption.

In the embodiment illustrated in Fig. 2, the prosthetic meniscus 10 includes a mesh member 20 extending from its peripheral edge. The mesh member 20 is composed of a nonantigenic, dissolvable suture material, and provides a readily used means for anchoring the meniscus 10 in place. The mesh member 20 may function in this capacity until sufficient tissue ingrowth occurs to then provide that function. By way of an example, the mesh member 20 may be a # 1 mesh screen composed of absorbable suture materials such as polyglyconate, Dexon or polydioxane (PDS) woven into a mesh. Nonabsorbable suture materials such as Gore-tex may also be used.

Figs 4 and 5 show additional embodiments of the present invention which are similar in composition of the prosthetic meniscus depicted in Fig. 2. More particularly, Fig. 4 depicts a right circular cylinder-shaped meniscus 22. Fig. 5 shows a sectional view along line 5-5 of the meniscus shown in Fig. 4.

In other forms of the invention, still other shapes may be used, particularly with varying densities of collagen fibers and dispersions of GAG molecules and crosslinks, permitting accommodation of differing stress levels, rates of ingrowth, and resiliency.

Exemplary menisci may be constructed in the following manner:

EXAMPLE I

(A) Type I collagen from bovine Achilles tendon is mechanically processed to disintegrated tissue, soaked in 0.1% N HCl and mechanically compressed under high pressure while methodically narrowing the gap between metal rollers. Swollen collagen fibers are dehydrated in 20% NaCl for 3 days, and the mechanical separation repeated. Final mechanical separation is repeated at pH 3.0-3.5 in the presence of 0.7% NaCl. The deswollen fibers produce 20 to 30 centimeter long fibers at pH 3.0-3.5. These fibers are ground into a dispersion and further washed in 0.7% NaCl and neutralized in the presence of 0.1% HCl as described above. They are then suspended in a 20% NaCl solution. Ethanol may be added to decrease the isoelectric point and further increase the concentration of collagen fibers in the dispersion.

(B) The fiber dispersion is then subjected to dehydrothermal crosslinking conditions: heating to from about 100 to 135 degrees C for about 24 to 72 hours, and then further crosslinked by exposure for 1-15 hours to 0.1-0.5% glutaraldehyde at room temperature.

(C) Further neutralization and washes with a balanced electrolyte solution containing 20% NaCl and 25% acetone in 0.5 M phosphate buffer, pH 5.5 are carried out. Multiple washes in the buffered salt-acetone solution also containing 0.5 M EDTA are also performed. The final rinse step includes 0.15 M phosphate buffer, 7.2, with drying in preformed meniscal molds.

EXAMPLE II

(A) - (C) same as steps (A) - (C) described in EXAMPLE I.

(D) While in dispersion form, selected glycosaminoglycans are added which may include chondroitin 6-sulfate, chondroitin 4-sulfate, hyaluronate, dermatan sulfate, heparin sulfate, and keratin sulfate to a concentration of about 0.5-25 weight %, preferably to about 2.5 weight %. The GAGs are allowed to diffuse freely in the solution, creating a porous matrix with properties defined by the pore sizes of 30-60 microns, the purity of the collagen at 99.9%, the density of the structure, and the quantity of GAGs.

EXAMPLE III

(A) - (D) same as steps (A) - (D) as described in Example II.

(E) For attachment purposes, a mesh of absorbable polyglyconate suture material, matched to the size of the mold, in laid in the dispersed collagen such that it protrudes from the structure's periphery to form a skirt which may extend over the tibial plateau. This mesh provides both immediate attachment sites and long term fibrous ingrowth.

EXAMPLE IV

(A)-(C) same as steps (A) - (C) as described in EXAMPLES I and II.

(D') While in dispersion form, selected glycosaminoglycans are added. The dispersion is then subjected to pressurization to 89 kN (20,000 lbs) compressing the structure to reduce the pore sizes to 10-50 microns.

(E) same as step (E) as described in EXAMPLE II.

EXAMPLE V

(A) same as step (A) as described in EXAMPLES I - IV.

(B) The fiber dispersion is then crosslinked by exposure for 1 - 15 hours to 0.05 M 1-ethyl-3-(3-dimethylaminopropyl) carbodiimide-HCl in a balanced electrolyte solution at pH 5.0 at room temperature.

(C) same as step (C) as described in EXAMPLES I - IV.

(D) same as step (D) as described in EXAMPLES II and III.

EXAMPLE VI

(A) same as step (A) as described in EXAMPLES I - V.

(B) The fiber dispersion is then subjected to dehydrothermal crosslinking conditions: heating to from about 100 to 135 degrees C for about 24 to 72 hours, and then further crosslinked by exposure for 1-15 hours to 0.05 M 1-ethyl-3-(3-dimethylaminopropyl) carbodiimide-HCl in a balanced electrolyte solution, pH 5.0 at room temperature.

Other chemical crosslinking reagents known to those skilled in the art (such as hexamethylene diisocyanate) may be substituted for glutaraldehyde or carbodiimide in the above EXAMPLES.

With the processes described in the above examples, a prosthetic meniscus of the form shown in Figs. 2 and 3 may be constructed having the following dimensions:

height A = (0.20 - 40 inches) 5.1-10.2 mm
angle B = 25° - 45° degrees
radius C = (0.5 - 2.0 inches) 12.7-51 mm
height D = (0.05 - 0.1 inches) 1.3-2.5 mm

Generally, that exemplary meniscus has substantially uniform GAG concentration of approximately 50 mg/ml of tissue, and crosslink density as expressed by the 3-hydroxy pyridinium crosslink/collagen molar ratio of 0.86 when the collagen has a content of >85% by dry weight. In the preferred form, the functional characteristics of the exemplary meniscus after repopulation with host meniscal fibrochondrocytes are as set forth in Table 1.

TABLE 1

Physiologic Loading Rate:	70 - 100 kg/cm^2/sec
Strain Rate:	1.7 - 9 %/sec
Breaking Strain:	15 - 25%
Modulus of Elasticity: (of hydrated tissue after creep)	0.412 mPa
Modulus of Superficial (200 um) Isotropic Fibers:	45 - 65 mPa
Modulus of Deep Anisotropic Fibers:	
Circumferential Fibers:	
Superficial	35 - 55 mPa
Middle	185 - 205 mPa
Deep	130 - 150 mPa
Radial Fibers:	
Superficial	65 - 80 mPa
Middle	1 - 4 mPa
Deep	3 - 6 mPa
Average Permeability Density Coefficient:	8.13 x 10^{-15} m^4/N.s.
Coefficient of Friction	0.001 when covered in synovial fluid

The invention may be embodied with other specific forms. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description.

Claims

1. A prosthetic meniscus comprising a dry porous matrix of biocompatible bioresorbable fibers, which fibers include natural polymers or analogs or mixtures thereof, characterised by the fiber matrix being adapted to have in vivo an outer surface contour substantially the same as that of a natural meniscus, and comprising a three-dimensional array of Type I collagen fibers interspersed with glycosaminoglycan molecules, wherein said collagen fibers are present at a concentration of 65%-98% by dry weight, wherein said glycosaminoglycan molecules are present at a concentration of 1%-25% by dry weight, and wherein at least a portion of said molecules provide glycosaminoglycan crosslinks between said collagen fibers.

2. The prosthetic meniscus of claim 1, wherein said array is in the shape of a cylindrical pad or is substantially wedge-shaped, e.g. crescent-shaped, having a wide central region between two narrow distal tip regions.

3. The prosthetic meniscus of claim 1, wherein said glycosaminoglycan molecules consist of at least one of the group comprising: chondroitin 4-sulfate; chondroitin 6-sulfate; keratin sulfate; dermatan sulfate; heparin sulfate; and hyaluronic acid.

4. The prosthetic meniscus of claim 1, wherein said crosslinks consists of at least one of the group of glycosaminoglycan molecules comprising: chondroitin 4-sulfate; chondroitin 6-sulfate; keratin sulfate; dermatan sulfate; heparan sulfate; and hyaluronic acid, and wherein the molecular weight of said molecular crosslinks is within the range of 800--60,000 daltons.

5. The prosthetic meniscus of claim 4, which permits ingrowth of and provides support for regenerated meniscal tissue; by for example said glycosaminoglycan crosslinks being present at a density less than about 0.95 and greater than about 0.50 crosslink/collagen ratio.

6. The prosthetic meniscus of any one of claims 1 to 5, wherein the orientation of said collagen fibers is substantially random throughout said meniscus; or the orientation of said collagen fibers is ordered substantially throughout said array, said array comprising substantially circumferentially extending and radially extending fibers.

7. The prosthetic meniscus of any one of claims 1 to 6, wherein the density of said collagen fibers is substantially uniform throughout said array.

8. The prosthetic meniscus of any one of claims 1 to 6, wherein the dispersion of said glycosaminoglycan molecules is substantially uniform throughout said array.

9. The prosthetic meniscus of any one of claims 1 to 6, wherein the density of said collagen fibers is substantially non-uniform throughout said array.

10. The prosthetic meniscus of any one of claims 1 to 6, wherein the dispersion of said glycosaminoglycan molecules is substantially non-uniform throughout said array, said crosslinks having for example relatively high density at the tip regions of said array, and relatively low density at the central region.

11. The prosthetic meniscus of any one of claims 1 to 10, further comprising a mesh extending from portions of the outer surface of said array, said mesh being dissolvable and nonimmunogenic.

Patentansprüche

1. Prothetischer Meniscus, der eine trockene poröse Matrix von biokompatiblen bioresorbierbaren Fasern aufweist, die natürliche Polymere oder Analoga oder Gemische davon aufweisen,
dadurch gekennzeichnet, daß die Fasermatrix aufgebaut ist, um in vivo eine Außenflächenkontur zu haben, die im wesentlichen die gleiche wie die eines natürlichen Meniscus ist, und eine dreidimensionale Anordnung von Collagenfasern vom Typ I, durchsetzt mit Glucosaminoglykan-Molekülen, aufweist, wobei die Collagenfasern in einer Konzentration von 65-98 %, bezogen auf die Trockenmasse, vorhanden sind, wobei die Glucosaminoglykan-Moleküle in einer Konzentration von 1-25 %, bezogen auf die Trockenmasse, Vorhanden sind, und wobei zumindest ein Teil dieser Moleküle Glucosaminoglykan-Brücken zwischen den Collagenfasern bildet.

2. Prothetischer Meniscus nach Anspruch 1, wobei die Anordnung in Form einer zylindrischen Scheibe vorliegt oder im wesentlichen keilförmig, z. B. sichelförmig, ist, wobei sie einen breiten zentralen Bereich zwischen zwei schmalen distalen Spitzen hat.

3. Prothetischer Meniscus nach Anspruch 1, wobei die Glucosaminoglykan-Moleküle aus wenigstens einer Substanz der Gruppe bestehen, die aufweist: Chondroitin-4-sulfat; Chondroitin-6-sulfat; Keratinsulfat; Dermatansulfat; Heparinsulfat; und Hyaluronsäure.

4. Prothetiscner Meniscus nach Anspruch 1, wobei die Brücken aus wenigstens einer der Gruppen von Glucosaminoglykan-Molekülen bestehen, die aufweist: Chondroitin-4-sulfat; Chondroitin-6-sulfat; Keratinsulfat; Dermatansulfat; Heparinsulfat; und Hyaluronsäure, und wobei das Molekulargewicht der molekularen Brücken im Bereich von 800-60.000 Dalton liegt.

5. Prothetischer Meniscus nach Anspruch 4, der das Einwachsen von regeneriertem Meniscusgewebe zuläßt und es abstützt; indem beispielsweise die Glucosaminoglykan-Brücken in einer Dichte von kleiner als 0,95 und größer als ca. 0,50 Brücken/ Collagen-Verhältnis vorhanden sind.

6. Prothetischer Meniscus nach einem der Ansprüche 1-5, wobei die Orientierung der Collagenfasern durch den gesamten Meniscus im wesentlichen willkürlich ist; oder die Orientierung der Collagenfasern im wesentlichen durch die gesamte Anordnung geordnet ist, wobei die Anordnung im wesentlichen umfangsmäßig verlaufende und radial verlaufende Fasern aufweist.

7. Prothetischer Meniscus nach einem der Ansprüche 1-6, wobei die Dichte der Collagenfasern durch die gesamte Anordnung im wesentlichen gleichförmig ist.

8. Prothetischer Meniscus nach einem der Ansprüche 1-6, wobei die Verteilung der Glucosaminoglykan-Moleküle durch die gesamte Anordnung im wesentlichen gleichförmig ist.

9. Prothetischer Meniscus nach einem der Ansprüche 1-6, wobei die Dichte der Collagenfasern durch die gesamte Anordnung im wesentlichen ungleichförmig ist.

10. Prothetischer Meniscus nach einem der Ansprüche 1-6, wobei die Verteilung der Glucosaminoglykan-Moleküle durch die gesamte Anordnung im wesentlichen ungleichförmig ist, wobei die Brücken beispielsweise relativ hohe Dichte an den Endbereichen der Anordnung und relativ niedrige Dichte an dem zentralen Bereich haben.

11. Prothetischer Meniscus nach einem der Ansprüche 1-10, der ferner ein Netzwerk aufweist, das von Bereichen der Außenfläche der Anordnung ausgeht, wobei das Netzwerk auflösbar und nichtimmunagenetisch ist.

Revendications

1. Ménisque prothétique, comprenant une matrice poreuse sèche de fibres biocompatibles biorésorbables, lesquelles fibres contiennent des polymères naturels, des analogues ou des mélanges de ceux-ci, caractérisé en ce que la matrice de fibres est adaptée de façon à présenter in vivo un profil de la surface externe qui est sensiblement la même que celui d'un ménisque naturel, et est composée d'un réseau tridimensionnel de fibres de collagène de type I entremêlées de molécules de glycosaminoglycanne, réseau dans lequel lesdites fibre de collagène sont présentes à une concentration de 65-98% en poids a sec, lesdites molécules de glycosaminoglycanne sont présentes à une concentration de 1-25% en poids à sec, et une partie au moins desdites molécules créent des liaisons croisées de glycosaminoglycanne entre lesdites fibres de collagène.

2. Ménisque prothétique selon la revendication 1, dans lequel ledit réseau est sous la forme d'un bloc cylindrique ou a sensiblement la forme d'un coin, par exemple en forme de croissant, présentant une région centrale large entre deux régions de pointe distale étroites.

3. Ménisque prothétique selon la revendication 1, dans lequel lesdites molécules de glycosaminoglycanne consistent en l'un au moins des éléments du groupe comprenant le chondroïtine-4-sulfate, le chondroïtine-6-sulfate, le kératanne-sulfate, le dermatanne-sulfate, l'héparanne-sulfate, et l'acide hyaluronique.

4. Ménisque prothétique selon la revendication 1, dans lequel lesdites liaisons croisées consistent en l'au moins des éléments du groupe de molécules de glycosaminoglycanne comprenant le chondroïtine-4-sulfate, le chondroïtine-6-sulfate, le kératanne-sulfate, le dermatanne-sulfate, l'héparanne-sulfate et l'acide hyaluronique, et dans lequel le poids moléculaire se situe dans la gamme de 800 à 60 000 daltons.

5. Ménisque prothétique selon la revendication 4, qui permet la croissance interne du tissu méniscal régénéré et fournit un support à celui-ci, par le fait par exemple que lesdites liaisons croisées de glycosaminoglycanne sont présentes avec une densité inférieure à un rapport liaisons croisées/collagène d'environ 0,95 et supérieure a un rapport d'environ 0,50.

6. Ménisque prothétique selon l'une quelconque des revendications 1 à 5, dans lequel l'orientation desdites fibres de collagène est aléatoire pratiquement dans tout le ménisque, ou orientation desdites fibres de collagène est ordonnée pratiquement dans tout ledit réseau, ce réseau comprenant essentiellement des fibres qui s'étendent circonférentiellement et des fibres qui s'étendent radialement.

7. Ménisque prothétique selon l'une quelconque des revendications 1 à 6, dans lequel la densité desdites fibres de collagène est pratiquement uniforme dans tout ledit réseau.

8. Ménisque prothétique selon l'une quelconque des revendications 1 à 6, dans lequel la dispersion desdites molécules de glycosaminoglycanne est pratiquement uniforme dans tout ledit réseau.

9. Ménisque prothétique selon l'une quelconque des revendications 1 à 6, dans lequel la densité desdites fibres de collagène est essentiellement non uniform dans tout ledit réseau.

10. Ménisque prothétique selon l'une quelconque des revendications 1 à 6, dans lequel la dispersion desdites molécules de glycosaminoglycanne est essentiellement non uniforme dans tout ledit réseau, lesdites liaisons croisées ayant par exemple une densité relativement élevée dans les régions des pointes dudit réseau et une densité relativement faible dans la région centrale.

11. Ménisque prothétique selon l'une quelconque des revendications 1 à 10, comprenant en outre un élément à mailles s'entendant depuis des parties de la surface externe dudit réseau, cet élément à mailles étant résorbable et non immunogène.

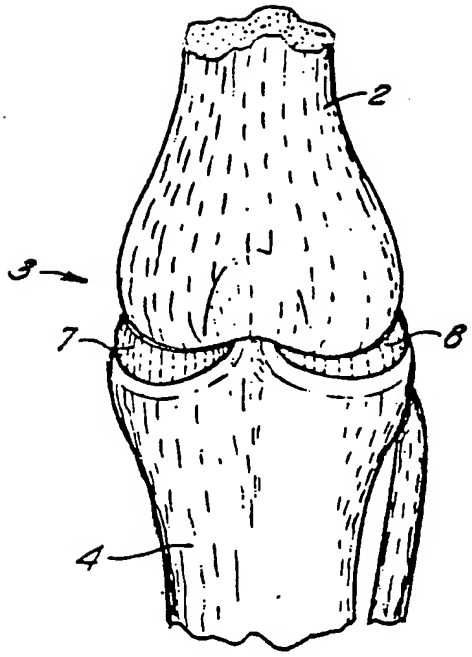
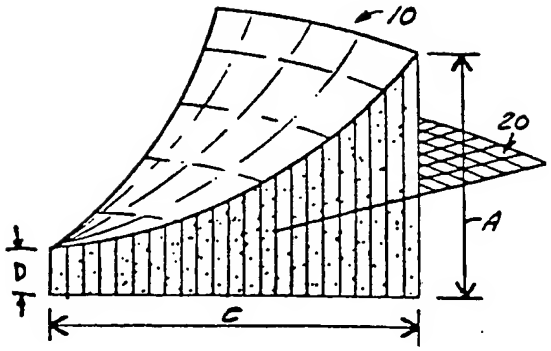


FIG. 1

FIG. 3



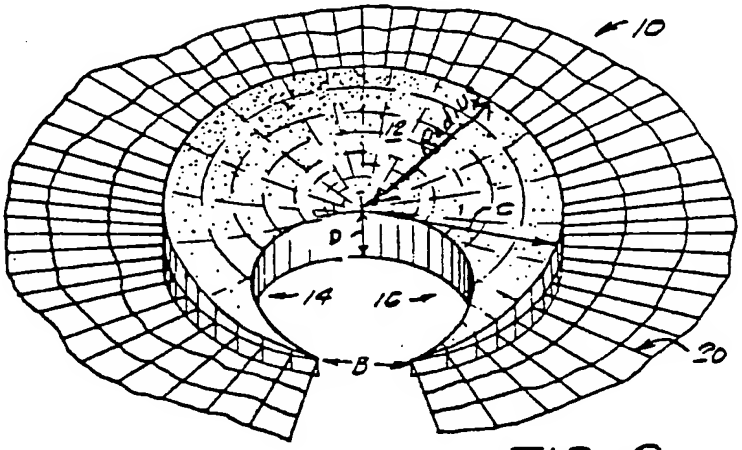


FIG. 2

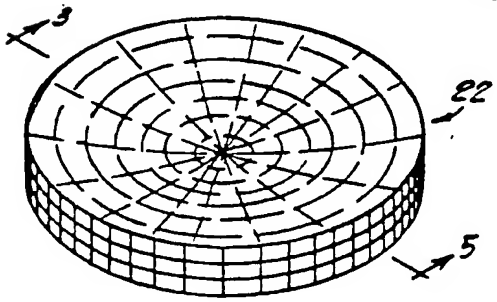


FIG. 4

FIG. 5